## Revised

Economic Impact Assessment Per Government Code Section 11346.3, subdivision (b):

For amendments to CIRM Intellectual Property Regulations

Dated: November 22, 2013

<u>Action:</u> The regulatory action amends the existing intellectual property and revenue sharing requirements for non-profit and for-profit entities (sections 100600 et seq.). The amendments refine the procedures and requirements attendant to applying for, receiving and expending CIRM research funds. The action does not regulate a commercial or private activity of any individual or institution but reaches only administrative functions of institutions and their licensees in connection with the use of CIRM research funds and exploitation of CIRM-funded intellectual property.

## Impact:

Under section 3 of the "California Stem Cell Research and Cures Act," which established the California Institute for Regenerative Medicine, funds for this agency are continuously appropriated without regard to fiscal year and not subject to budgetary control. By statute, this agency requires strict fiscal and public accountability through mandatory independent audits.

CIRM has determined that that proposed regulatory action has no impact on small businesses. The regulation implements conditions on awarding grants for stem cell research. This research will be conducted almost exclusively by large public and private non-profit institutions, as well as large for-profit institutions. As such, and the regulations are not expected to adversely impact small business as defined in Government Code section 11343.610. Application for grant funds is voluntary and grant awards are required by Proposition 71 to include a prescribed additional amount to cover any costs associated with administration of the grant by grant recipients.

This action is not expected to have a direct impact on the creation or elimination of jobs, nor the creation of new businesses or elimination of existing businesses, nor the expansion of business currently doing business within the State of California because the amendments affect only administrative requirements regarding use of grant funds. The use of grant funds is required neither by law nor these regulations. To the extent the regulations facilitate use of the funds and encourage development of intellectual property and return to the state as required by law, and to the extent California institutions apply for and receive research funds, such requirements are indirectly attributable to increased economic activity spurred by the investment research funds in the state and resultant positive business and employment development. Also, to the extent the amendments makes

it possible for the expenditure of research funds in the state, and to the extent that research results in medical treatments and cures for chronic disease and injury, the amendments indirectly benefit the health and welfare of California residents who will benefit from such treatments and cures.